K130874

stryker

Navigation

SEP 2 7 2013

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

Applicant Name:	Stryker Leibinger GmbH & Co. KG - Navigation Boetzinger Strasse 41 D-79111 Freiburg, Germany Phone number: +49-761-4512117 Fax number: +49-761-451249117
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Date prepared:	24 September 2013

2. Device Name

Trade Name:	Stryker NAV3i Platform				
Common Name:	Navigation System Platform				
Classification Name:	Product Code	Device	Regulation Number	Class	Review Panel
	Primary Code: HAW	Neurologic stereotaxic instrument	21 CFR §882.4560	II	Neurology
	Secondary Code: OLO	Orthopedic stereotaxic instrument	21 CFR §882.4560	II	Orthopedic

3. Legally Marketed Predicate Device

The legally marketed predicate device is the Cart I Platform (trade name: Stryker Navigation Cart) as cleared in K002732 Stryker Navigation System - ENT Module.

510(k) Number	Product Code	Trade Name	Manufacturer
K002732	HAW	Stryker Navigation Cart	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany

4. Device Description

The Stryker NAV3i Platform is a modular component of the Stryker Navigation System and is intended to run Stryker Navigation surgical software for surgical procedures using stereotactic techniques. The surgical navigation software used on this device is cleared as a separate 510(k).

The Stryker Navigation System is a planning and intraoperative guidance system which assists in various surgical procedures. It allows for the localization of surgical instruments and visualization of their position relative to patient specific images and/or patient specific anatomical landmark information assisting the surgeon in performing the intervention at a high level of precision. For localization, active optical tracking based on infrared light is used. Using three linear sensors, the Navigation Camera detects signals from infrared light emitting diodes which are attached to the instruments to be localized.

The NAV3i Platform consists of a mobile cart, a computer system, a monitor and a Navigation Camera. During surgery, the platform is placed close to the operating room table but not within the sterile field. Articulated arms allow for the alignment of the Navigation Camera and the monitor to the operative field. The NAV3i Platform features interfaces for entering medical images such as CT images, MRI images or microscope images which are required for navigation. The computer is used to install and run Stryker Navigation Application Software, while the monitor conveys navigation information to the user.

There are two reasons for the traditional 510(k) submission. Firstly, it is intended to "unbundle" the clearance of the platform from the Stryker Navigation System as a whole. The predicate device submission included the platform as a component of the Stryker Navigation System - ENT Module. Secondly, some design modifications have been introduced to increase the user's comfort, to provide a more modern industrial design and to offer state-of-the-art technology for computer interfaces and components.

5. Indications for Use

The NAV3i Platform is a computer workstation that, when used with specific Stryker Navigation surgical software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient.

The clinical setting and target population for the NAV3i Platform is that of a patient undergoing a surgical procedure using stereotactic techniques.

6. Substantial Equivalence Comparison

The indications for use of the subject device Stryker NAV3i Platform are equivalent to the predicate device Cart I Platform for the Stryker Navigation System. Furthermore, the technological characteristics of the modified NAV3i Platform are substantially equivalent to the original Cart I Platform. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the NAV3i Platform is substantially equivalent to the predicate device.

The following table gives an overview of the substantial equivalence reflecting all modifications being made between the predicate device and the subject device.

Table 1

Topic	Predicate Device	Subject Device	Equivalence assessment
LiveCam (USB Video Camera)	LiveCam was not offered.	Built-in LiveCam allows for easy positioning of the Navigation Camera.	Equivalent: This feature did not exist in the predicate device but does not alter the operating principle nor is it affecting the essential performance.
Monitor	The main monitor used by the surgeon: 18 inch flat screen monitor mounted on an articulated arm.	The main monitor used by the surgeon: 32 inch flat screen monitor mounted on an articulated arm.	Equivalent: Changes do not affect the technology or the operating principle of the platform.
IO-Tablet	Contained mouse and keyboard.	Mouse and touch screen monitor with implemented keyboard functionality are integrated in the IO-Tablet, IO-Tablet doubles as operator's monitor for the OR staff.	Equivalent: Ergonomic improvements by intuitive touch functionality and state-of-the-art technology for a data input device do not change the performance specification.

Topic	Predicate Device	Subject Device	Equivalence assessment
Computer	Windows PC based on Intel architecture. Configured Windows NT operating system.	Windows PC based on Intel state of the art architecture. Configured Windows XP operating system.	Equivalent: Performance specification changes due to additional state of the art PC interfaces and a new version of the operating system.
RFID Card Reader for licensing and logistic reasons	Not existing.	RFID Card Reader for single case licensing integrated in the IO-Tablet.	Equivalent: The addition of the RFID Card Reader does not add any performance features and has no effect on the essential performance of the NAV3i Platform.
Network connectivity	Connection type: Standard Ethernet connection and modem connection.	Connection type: Standard Ethernet connection and WLAN connection.	Equivalent: The extended network connectivity does not add any performance features in regards to the indications for use of the NAV3i Platform.
Remote Service Connectivity	Remote service access by Virtual Network Computing (VNC) remote desktop service over network or modem connection.	Remote service access is offered by a remote access client over Ethernet or WLAN.	Equivalent: This represents the same technology for the remote service access.
Navigation Camera	Active optical measurement system localizing infrared light emitting diodes (LED) using three linear sensors and a working space of 1.00 meter in diameter. The system is encapsulated in two separate housings: the camera and the localizer computer.	Active optical measurement system localizing infrared light emitting diodes (LED) using three linear sensors and a working space of 1.25 meter in diameter. The system is encapsulated in one housing and is called Navigation Camera.	Equivalent: The modified design of the Navigation Camera does not impact the operating principle, control mechanism, technology or energy source. Therefore, the change does not affect the essential performance of the NAV3i Platform.

Topic	Predicate Device	Subject Device	Equivalence assessment
Power Supply	External power source: AC Power supply, 120V, 50/60Hz including off-the-shelf uninterruptible power supply (UPS) for power interruptions less than or equal to 10 minutes.	External power source: AC Power supply, 100/240V, 50/60Hz. including off-the-shelf uninterruptible power supply (UPS) for power interruptions less than or equal to 6 minutes.	Equivalent: The time difference does not alter the operating principle and does not raise new safety or effectiveness issues.
Articulated arms	Weight balanced articulated arms have the monitor and localization camera mounted. Approximately 1000 mm arms with three joints for camera and monitor movement are offered.	Same mechanical principal of spring arms with the same degrees of freedom. Change in arm lengths: monitor arm length is about 900 mm, Navigation Camera arm length is about 1300 mm.	Equivalent: Improved ergonomics for alignment and handling of the Navigation Camera and monitor in the OR space. The operating principle of the Platform is not affected.
Cart Housing	The Cart I Platform is equipped with 4 castors with brakes. The cart housing contains the computer, the computer interfaces as well as the two articulated arms carrying the camera and the monitor.	The NAV3i Platform is equipped with 4 castors with brakes and additional cable guards. The cart housing contains the computer, the computer interfaces as well as the two articulated arms carrying the Navigation Camera and the monitor.	Equivalent: The industrial design is changed but the mechanical structure and functioning is similar. The performance of the platform is not changed and no new safety and effectiveness issues are raised.
Dimensional Specifications	Outer dimensions: Length x Width x Height: 762 x 762 x 1880 mm Weight: 249.5 kg	Outer dimensions: Length x Width x Height: 960 x 720 x 1920 mm Weight: 250 kg	Equivalent: Only slight modifications which do not impact the performance of the Stryker Navigation Platform and do not raise new safety and effectiveness issues.

The following table gives an overview of all design features which remain the same between the predicate device and the subject device.

Table 2

Design features which remain the same	
Control mechanism	The Platform is controlled by a standard PC interface including mouse and keyboard input functions and a display. In addition, the Stryker Navigation Application Software can be remotely controlled by Stryker Smart Instruments over an infrared communication interface. During surgery, the software is controlled via Stryker Smart Instruments.
Operating principle	The Platform runs Stryker Navigation Application Software on a Windows PC based system. For patient data import and export, the Platform provides standard state-of-the-art storage media and network interfaces. For video import the system provides a standard state-of-the-art video interface to capture live video. The Platform offers an active optical localization device, i.e. the Navigation Camera. The Navigation Camera allows three-dimensional localization of the Stryker Smart Instruments which are equipped with LEDs by detecting the position of the light center of each infrared LED.
Movability	The Platform is equipped with four castors and is movable within a hospital.
General design	Both devices have articulated arms to carry the monitor and the camera and have a housing body to carry a Windows-based computer.
Microscope data interface	Both platform models encompass a microscope data interface.

The modifications do not alter the basic technology, do not raise any new issues regarding safety and effectiveness and support substantial equivalence of the subject device.

7. Non-clinical Testing

Validation activities, including usability testing, have been conducted to provide assurance that the device meets the performance requirements under the indications for use conditions. In addition, verification tests, such as electrical safety acc. to IEC 60601-1, have been performed to show that the device is safe and effective. The following table contains a complete list of all tests performed to support substantial equivalence, gives a basic description of the test procedure in the column "Basic description" and the conclusion or results obtained from the test in the column "Conclusion/Result".

Test	Basic description	Conclusion/Result
User Need Validation	Scope of the test is to validate the Indications For Use and the user needs of the NAV3i Platform under simulated use case situations.	Validation successful, all user needs met
Human Factors Engineering (HFE)	This test is conducted to validate the NAV3i Platform with respect to use errors following the FDA guidance paper *Draft Guidance for Industry and Food and Drug Administration Staff. Applying Human Factors and Usability Engineering to Optimize Medical Device Design.*	Validation successful, device safe and effective with respect to use errors
Safety Test regarding risk analysis	Implementation and effectiveness of all risk control measures specified in the NAV3i Platform risk analysis are tested and verified.	Risk Control measures are effective and mitigate the associated risks
Product Safety Test regarding medical electrical equipment	Compliance with AAMI/ANSI ES60601-1:2005/A1:2012 for medical electrical equipment is tested. Part 1: General requirements for basic safety and essential performance Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	Compliance with standards' requirements demonstrated, no deviations
Accuracy Test	The Stryker Navigation System's accuracy is tested using the NAV3i Platform, a Stryker Navigation Software Application, Smart Instruments and Accessories following the ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.	All accuracy specifications met with statistical significance

Test	Basic Description	Conclusion/ Result
Integration Tests with Stryker Navigation Software Applications	The NAV3i Platform is restricted to operation with Stryker Navigation Software Application Modules only. To demonstrate compatibility of the NAV3i Platform with existing Application Modules, integration tests have been performed. The integration of SpineMap 3D Navigation, OrthoMap 3D Navigation, Versatile Hip Navigation, Express Knee Navigation, Precision Knee Navigation, Fluoro Navigation, FluoroMap Navigation and CranialMap Navigation Software Application Modules has been tested with the NAV3i Platform according to Design Input requirements under simulated clinical use conditions.	All Application Modules meet specifications on NAV3i Platform as on previous platforms
Startup Reliability	Tested NAV3i Platform start up reliability over lifetime including Stryker Navigation Software Application Modules across multiple usages. The number of test samples and test runs required to simulate reliability over lifetime was defined using statistical methods.	Device electronically reliable over the specified lifetime
Robustness for every day use	Tested NAV3i Platform robustness by simulating transport inside hospital and intraoperative use over lifetime. The number of test samples and test runs required to simulate reliability over lifetime was defined using statistical methods.	Device mechanically robust over the specified lifetime
Shipment Test	Test of shipment conditions of the NAV3i Platform in transport cases was performed according to ASTM D 4169-09.	Device fully functional after shipment

All non-clinical tests successfully passed demonstrating that the subject device performs as safely and effectively as the predicate device and supporting substantial equivalence.

8. Clinical Testing

No clinical testing has been conducted.

9. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the NAV3i Platform performs as safely and effectively as the legally marketed device identified in section 3. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the NAV3i Platform is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Stryker Navigation
Ms. Lilian Eckert
Senior Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, Baden-Wuerttemberg 79111
Germany

Re: K130874
Trade/Device Name: NAV3i Platform
Regulation Number: 21 CFR 882.4560
Regulation Name: Neurologic Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, OLO
Dated: August 26, 2013
Received: August 28, 2013

Dear Ms. Eckert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130874

Device Name: Styker NAV3i Platform

Indications For Use:

The NAV3i Platform is a computer workstation that, when used with specific Stryker Navigation surgical software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient.
The clinical setting and target population for the NAV3i Platform is that of a patient undergoing a surgical procedure using stereotactic techniques.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130874